

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### **Analgesic effect of topical gel Silymarin versus placebo in patients with knee osteoarthritis: a double-blind randomized clinical trial**

#### **Protocol summary**

##### **Study aim**

To assess the analgesic effect of topical gel Silymarin versus placebo in patients with knee osteoarthritis

##### **Design**

This is a Phase III double-blind randomized clinical trial with a control group with parallel groups, in which eligible patients will be randomly assigned to the intervention and control groups using block randomization.

##### **Settings and conduct**

This study will be conducted at the Imam Khomeini Clinic in Hamadan city, involving 60 eligible patients with knee osteoarthritis. The patients will be randomly assigned to the intervention and control groups through the block randomization. This trial will be double-blinded.

##### **Participants/Inclusion and exclusion criteria**

Inclusion criteria: Age of 18 to 70 years Mild to moderate knee osteoarthritis Exclusion criteria: Inflammation of the knee artery Rheumatoid arthritis History of knee surgery

##### **Intervention groups**

Intervention group: Topical gel Silymarin 3% three times daily plus topical gel Piroxicam twice daily for 2 weeks  
Control group: Topical gel placebo three times daily plus topical gel Piroxicam twice daily for 2 weeks

##### **Main outcome variables**

Primary outcome: Pain score Secondary outcome: Probable side effects (reddish, pruritus)

#### **General information**

##### **Reason for update**

##### **Acronym**

##### **IRCT registration information**

IRCT registration number: **IRCT20120215009014N498**

Registration date: **2024-02-21, 1402/12/02**

Registration timing: **prospective**

Last update: **2024-02-21, 1402/12/02**

Update count: **0**

##### **Registration date**

2024-02-21, 1402/12/02

##### **Registrant information**

###### **Name**

Jalal Poorolajal

###### **Name of organization / entity**

Department of Epidemiology & Biostatistics Hamadan University of Medical Sciences

###### **Country**

Iran (Islamic Republic of)

###### **Phone**

+98 81 1838 0090

###### **Email address**

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##### **Recruitment status**

**Recruitment complete**

##### **Funding source**

##### **Expected recruitment start date**

2024-04-06, 1403/01/18

##### **Expected recruitment end date**

2024-07-08, 1403/04/18

##### **Actual recruitment start date**

empty

##### **Actual recruitment end date**

empty

##### **Trial completion date**

empty

##### **Scientific title**

Analgesic effect of topical gel Silymarin versus placebo in patients with knee osteoarthritis: a double-blind randomized clinical trial

##### **Public title**

Analgesic effect of topical gel Silymarin versus placebo in patients with knee osteoarthritis

##### **Purpose**

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Age of 18 to 70 years Mild to moderate knee osteoarthritis

### Exclusion criteria:

Inflammation of the knee artery Rheumatoid arthritis  
History of knee surgery

## Age

From **18 years** old to **70 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **60**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this study, random assignment of patients to the intervention and control groups will be carried out using block randomization. To achieve this, four sheets of paper will be prepared - two with the name of the intervention and two with the name of the control. These paper sheets will be pooled and placed in a container. Patients will be selected one at a time without replacement, and for each patient, a paper sheet will be randomly drawn from the container. After each draw, the paper sheets will be returned to the container, and the process will be repeated until the desired sample size is reached.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

Both the medications and placebos will have the same shape. Consequently, patients will remain unaware of the type of intervention they receive. Moreover, the randomization process will be conducted by a separate individual from the one who examines the patients, ensuring that the examining person remains unaware of the intervention. Therefore, the trial will be conducted as a double-blind study.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

#### Street address

Vice-chancellor for Research and Technology,  
Hamadan University of Medical Sciences, Fahmideh Ave

#### City

Hamadan

#### Province

Hamadan

#### Postal code

6517838695

#### Approval date

2024-02-10, 1402/11/21

#### Ethics committee reference number

IR.UMSHA.REC.1402.689

## Health conditions studied

### 1

#### Description of health condition studied

##### ICD-10 code

##### ICD-10 code description

### 2

#### Description of health condition studied

Osteoarthritis of knee

##### ICD-10 code

M17

##### ICD-10 code description

Osteoarthritis of knee

## Primary outcomes

### 1

#### Description

Pain score

#### Timepoint

Before the intervention and 2 weeks later

#### Method of measurement

Using Visual Analog Scale (VAS)

## Secondary outcomes

### 1

#### Description

Probable side effects (reddish, pruritus)

#### Timepoint

2 weeks after the intervention

#### Method of measurement

By history taking and physical examination

## Intervention groups

### 1

#### Description

Intervention group: Topical gel Silymarin 3% three times daily plus topical gel Piroxicam twice daily for 2 weeks

**Category**

Treatment - Drugs

2

**Description**

Control group: Topical gel placebo three times daily plus topical gel Piroxicam twice daily for 2 weeks

**Category**

Placebo

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Imam Khomeini Clinic in Hamadan city

**Full name of responsible person**

Hamid Reza Heydari

**Street address**

Imam Khomeini Clinic, Mirzadeh Eshghi Ave.

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**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Dr. Reza Shokoohi

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**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Hamedan University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin**

**Type of organization providing the funding**

Academic

**Person responsible for general inquiries**

**Contact**

**Name of organization / entity**

Hamedan University of Medical Sciences

**Full name of responsible person**

Hamid Reza Heydari

**Position**

Student of Pharmacy

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Medical Pharmacy

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**Contact**

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**Position**

Pharmacologist

**Latest degree**

Ph.D.

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Hamedan University of Medical Sciences  
**Full name of responsible person**  
Dr. Jalal Poorolajal  
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Professor of Epidemiology  
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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available